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UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC
SHERR-UNA BOOKER, an individual, Plaintiff, v. C.R. BARD, INC., a New Jersey corporation and BARD PERIPHERAL VASCULAR, an Arizona corporation, Defendants.	**PLAINTIFF'S MOTION *IN LIMINE* #10 AND MEMORANDUM IN SUPPORT TO EXCLUDE EVIDENCE THAT DEFENDANTS NEEDED FDA CONSENT BEFORE ADDING A WARNING TO ITS LABELING OR ISSUING A RECALL** (The Honorable David G. Campbell) (Oral Argument Requested)

MEMORANDUM IN SUPPORT OF PLAINTIFF'S MOTION IN LIMINE TO EXCLUDE EVIDENCE THAT DEFENDANTS NEEDED FDA CONSENT BEFORE ADDING A WARNING TO ITS LABELING OR ISSUING A RECALL

Plaintiffs seek a pretrial ruling to preclude Defendants from commenting on, referring to, or introducing argument or evidence at trial that suggests Defendants needed consent from the FDA to add a warning to its label, send warning letters to physicians or consumers, or recall the G2 IVC Filter from the market.

MEMORANDUM OF LAW

The Supreme Court has clearly expressed that "the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an

adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." *Wyeth v. Levine*, 555 U.S. 555, 571 (U.S. 2009). FDA regulations also specifically allow a manufacturer to recall its medical device at any time. 21 C.F.R. § 7.46, titled "Firm-initiated recall," states, "A firm may decide of its own volition and under any circumstances to remove or correct a distributed product."

Furthermore, Bard's own Senior Marketing Manager, Janet Hudnall, specializing in the G2 line of IVC filters, admitted that Bard removed the previous version of the G2 filter, the Recovery filter, from the market once the newer G2 line was available. *See* Deposition Testimony of Janet Hudnall, Nov. 1, 2013, Exhibit A, at 136:3-12. Bard also testified through its corporate representative in a Rule 30(b)(6) deposition that manufacturers can voluntarily remove products from the market. Deposition Testimony of Chad Modra, Mar. 28, 2013, Exhibit B, at 169:2-169:17.

Bard also could have sent letters voluntarily to physicians in order to warn them of the increased risks of migration, perforation, tilt, and fracture associated with its products. Bard itself admits that in safety-related events—such as a misbranding—Bard could have sent letters to customers informing them of the event. Chad Modra testified on behalf of Bard that, after a misbranding, Bard could take "various forms of action, and that would include sending a letter to customers . . . ." (Exhibit B, at 167:24-169:8.) Nothing, including FDA agreement, consent, or command precluded Bard from providing many levels of warning of the increased risk of migration, perforation, tilt, and fracture it became aware of associated with its G2 line of filters.

Therefore, Bard should be precluded from arguing and putting into evidence anything that insinuates it could not have taken appropriate steps to voluntarily change its labeling[1] to add a warning, send letters to its customers, or effectuate a voluntary removal/recall from the market. Such evidence is not relevant and its probative value is

[1] Labeling is not limited to the IFU, it relates to all printed or graphic material regarding a medical device. 21 U.S.C. 321(m).

substantially outweighed by confusion of the issues, misleading the jury, and being unnecessarily time-consuming. Fed. R. Evid. 401, 402, 403.

Based upon the foregoing, Plaintiffs respectfully move the Court *in limine* to enter an Order granting this motion and precluding Defendants from commenting on, referring to, or introducing evidence that suggests that Defendants needed consent from the FDA to add a warning to its label, send warning letters to physicians/consumers, or recall its filters.

RESPECTFULLY SUBMITTED this 26th day of January, 2018.

GALLAGHER & KENNEDY, P.A.

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CERTIFICATE OF SERVICE

I hereby certify that on this 26th day of January, 2018, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Gay Mennuti